Patient Priorities Care (PPC) for Older Adults with Multiple Chronic Conditions Achieved through Primary and Specialty Care Alignment

Protocol

Patient Priorities Care Protocol, Version 2.0
March 21, 2018

Patient Priorites Care (PPC)

Principal Investigator:

Mary Tinetti, MD

Co-Investigator:

Caroline Blaum, MD

Supported by:

The John A. Hartford Foundation

Gordon and Betty Moore Foundation

Robert Wood Johnson Foundation

Patient-Centered Outcomes Research Institute

Version 2

TABLE OF CONTENTS

PRÉCIS

Study Title

Patient Priorities Care for Older Adults with Multiple Chronic Conditions Achieved through Primary and Specialty Care Alignment: Patient Priorities Care (PPC)

Objectives

- Evaluate the effect of this alignment on patient, clinician, and health system outcomes

Design and Outcomes

The design is a mixed-methods, pilot study with data collection occurring through quantitative interviews, qualitative interviews, and health encounters in the medical record. There are two study arms: (1.) the intervention which involves the delivery of Patient Priorities Care (PPC) and (2.) the control which involves standard clinical care. Patients are assigned to intervention or control arms based on their primary care practice location. The pilot study will take place at two primary care practices in Bristol, Connecticut that will be selected to ensure that the two sites' participants and clinicians are comparable. To understand communication and adoption of PPC across specialties, a cardiology practice will also be selected and trained for the intervention arm. The quantitative design uses a quasi-experimental, untreated control group design with pretest and posttest measurements and the qualitative design uses a purposive sampling method and semi-structured, in-depth interviews.

Clinician-Level Data Collection	Qualitative Data Collection (intervention arm): • Phone and In-Person Interviews
Patient-Level Data Collection	Qualitative Data Collection (15-25 intervention patients) • Phone and In-Person Interviews Quantitative Data Collection (150-250 control patients and 150-250 intervention patients) • Phone Interviews (6-9 months) • Medical Records (1 year) o Chronic conditions present within 1-year prior enrollment o Evidence of patient goal- and preference-focused decision-making o Health care utilization o Medications

Interventions and Duration

Patient Priorities Care is an innovative approach to shared decision-making that draws from

existing professional training (e.g. clinical competencies, motivational interviewing, and geriatrics care). Patient Priorities Care requires the elicitation and documentation of patient health outcome goals and care preferences and the alignment of clinical care with goals and priorities to achieve patients' health outcome goals and reduce the burden of multi-morbidity. Participants will be enrolled in the Patient Priority Care Program and meet with a trained goal facilitator to elicit their preferences, priorities, and goals. This information will be documented and shared with the clinicians who will then use the Patient Priorities Care approach with patients to inform and guide treatment decisions. Patients will participate in the program and be followed for one year from the goal elicitation visit.

Sample Size and Population

The clinicians and patient population will be recruited from a multi-site primary care group practice that coordinates care with area hospitals and specialty practices. The patient population is older adults with multiple chronic conditions (MCC).

Intervention Arm (Implementing Patient Priorities Care):

- 150-250 patients
- Primary Care Clinic (5-10 Clinicians)
- Cardiology Practice (5 Cardiologists)
- Goal Facilitators (2 Trained Staff)

Control Arm (Standard Clinic Care):

- A Primary Care Clinic (5-10 Clinicians) - selected to be comparable to the intervention practice in clinician and patient demographic characteristics.
- 150-250 patients

STUDY TEAM ROSTER

Principal Investigator: Mary Tinetti, MD

367 Cedar Street,
Harkness Bldg.
New Haven, CT 06518
(203) 688-5238
mary.tinetti@yale.edu

Co-Investigators: Caroline Blaum, MD

550 First Ave.
BCD 612
New York, NY 10016
Telephone: (646)501-2323
Fax: (646)501-2399
Caroline.Blaum@nyumc.org

PARTICIPATING STUDY SITES

The Family Medical Group
25 Collins Road
Bristol, CT 06010

Meriden Family Practice
816 Broad Street
Meriden, CT 06450

Bristol Cardiovascular Associates
22 Pine Street, #304
Bristol, CT 06010

1 STUDY OBJECTIVES

1.1 Primary Objective

- Assess the feasibility of aligning primary and specialty care to focus on the health priorities (i.e. specific and actionable outcome goals and care preferences) of older adults with multiple chronic conditions (MCC)

1.2 Secondary Objectives

- Evaluate the effect of this alignment on patient, clinician, and health system outcomes
- Learn from Primary Care Clinicians and cardiologists taking care of these patients how they translate people's goals and preferences into decision-making and care

2 BACKGROUND AND RATIONALE

2.1 Background on Condition, Disease, or Other Primary Study Focus

Healthcare decision-making for persons with multiple chronic conditions (MCC) is difficult.[1-5] The focus on managing individual conditions fails to account for interactions among multiple conditions and their treatments.[3,6] The magnitude of benefit for many treatments are modest in persons with MCC while risk of harm is increased. Evidence to guide care is often lacking because individuals with MCC are excluded from most clinical trials.[7,8] The uncertainty in the applicability of disease guidelines to this population makes decision-making difficult. Even trials that include older adults with MCC address disease-specific outcomes or survival, not necessarily the most valued outcomes.[2] Older adults with MCC are heterogenous and vary in both the outcomes that matter most and the healthcare they find acceptable.[9,10]

There is consensus that healthcare should be, "*respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.*"[11] Communication strategies facilitate patient preferences- and priorities-based decision-making for persons with serious illness or near the end-of-life.[12-15] However, methods for ascertaining the health priorities of older adults with multiple conditions who are not near the end-of life remain lacking, as do reliable approaches for aligning decision-making and care with these priorities. [1,2,9,10] Patient priorities refer to both patients' health outcome goals—what they want from their health care—and their healthcare preferences—what they are willing and able to do to achieve these health outcomes. In essence, patient priorities are patients' goals and preferences. Care that is inconsistent with patients' care preferences results in poor adherence.

Patients with multiple chronic conditions (multi-morbidity) report that the increasing number and complexity of tasks and activities required for healthcare management, such as medication regimens, healthcare visits, and self-management tasks are burdensome. While this approach to decision-making is appropriate for everyone, and is a core element of patient-centered care, it is particularly relevant for the 50-60% of older adults for whom disease guideline-driven care is of uncertain benefit but treatment remains focused on individual diseases.

Health care for adults with multiple conditions is complex with inherent trade-offs among desired outcomes or healthcare options. When faced with tradeoffs, people have different priorities for their health and healthcare. When patient priorities drive healthcare decisions, patients and clinicians can more appropriately address the inherent trade-offs arising from conflicting health goals, healthcare recommendations, and the burdens of such care. Elaborating clear and concise patient priorities that inform decision-making requires a reliable and efficient process for ascertaining patients' goals and preferences based on what matters most for patients across their multiple conditions.

Current clinical encounters do not typically provide the context or structure for promoting patient priorities conversations. Health professionals (e.g. geriatricians) who are traditionally trained in patient-centered communication using dedicated encounters can effectively elicit patient priorities, document them in the electronic health record (EHR), and communicate priorities to additional members of the patient's care team. However, training and implementation of the Patient Priorities Care process has not been adequately tested with other health professionals and settings.

Eliciting and documenting patient priorities is only the first step to adequately align patients' care with their goals and preferences. For complex, multimorbid patients, recommendations for medical, mental health, and social services should not be driven exclusively by disease categories or clinical guidelines. Care recommendations may work best when they are aligned with patient/caregiver goals and care preferences (i.e., patient priorities). Few prior initiatives have clarified the decision-making processes that clinicians (physicians, nurses, social workers, etc.) use to align care with patient priorities, including medical care, procedures, testing, and consultations. Additionally, there is no prior identification of best practices for implementing a structured process for eliciting preferences and aligning patient priorities with care. This protocol serves to pilot an initiative that will fill this gap.

2.2 Study Rationale

A potential solution to these problems is to move from decision-making predicated solely on disease-based guidelines to decision-making based on achieving each patient's most valued health outcome goals (e.g. relief of symptoms sufficient to allow particular functional activity) within the context of what they are willing and able to do (i.e. care preferences) to achieve these outcomes.

The core that defines patient priorities care is that:

- patients identify their health outcome goals and care preferences (collectively referred to as health priorities), and
- primary and specialty clinicians align their decision-making and care with these patients' health goals and preferences, considering patient preferences in the face of tradeoffs, including current treatment burden vs. risk of future health events

3 STUDY DESIGN

The design is a mixed-methods pilot study with data collection through quantitative interviews, qualitative interviews, and medical records. There are two study arms: (1.) the intervention (Patient Priorities Care) arm and (2.) the control (Standard Clinical Care) arm. A description of Patient Priorities Care can be found in STUDY INTERVENTIONS.

The quantitative component of the research uses a quasi-experimental untreated control group design with pretest and posttest measurements. The pilot will take place at two primary clinical care practices in Connecticut that are selected to ensure a similar clinician and patient population profile. To understand communication and adoption of PPC across specialties, a cardiology practice will also be selected and trained to implement PPC in the intervention arm. Patients will be assigned to intervention or control arms based on their primary care practice location. 150-250 patients in each arm will be enrolled and followed for up to 1 year with interviews and medical record reviews. Participants will undergo a baseline and follow-up interview to collect patient reported outcome measures. The interviewer assessor will be masked as to the nature of the intervention. Through medical record data, we will assess and compare health care utilization and evaluate clinical notes for evidence of PPC shared decision-making. The medical record adjudicators will be masked to the intervention as well as blinded to treatment assignment.

The qualitative component of the research uses a uses a purposive sampling method and semi-structured, in-depth interviews. Qualitative interviews will be conducted with the primary care clinicians, cardiologists, and goal facilitators as well as a subset of 15-25 patients receiving Patient Priorities Care.

4 SELECTION AND ENROLLMENT OF PARTICIPANTS

Participants will be enrolled at two Primary Care Clinical Practices within ProHealth Physicians, Inc. and an affiliated Cardiology Practice. ProHealth Physicians' practices are National Committee for Quality Assurance Patient-Centered Medical Homes and therefore meet defined standards for high quality primary care and relevant infrastructure. ProHealth Physicians, Inc. includes 415 primary care providers including MDs, Advanced Practice Registered Nurses, Physician's Assistants, and is a Centers for Medicare and Medicaid Innovation advanced payment Accountable Care Organization (ACO). The elicitation of patient priorities will be embedded into ProHealth Physicians' clinical programs routinely offered to patients. Select clinicians, designated as Goal Facilitators, will undergo training and preparation to elicit and document patients' health outcome goals, care preferences and priorities using patient-centered training materials and a Goals and Preferences template document (Appendix A).

The intervention patient population will involve older adults (age 66 or older) with multiple chronic conditions (MCC), who are Medicare patients receiving care through ProHealth Physicians, Inc. that are within the Accountable Care Organization (ACO) and receiving care in the Bristol practice. The age criteria ≥66 years was chosen to permit collection of Medicare data for the year before enrollment. Control patients will be enrolled through a comparable practice within ProHealth Physicians, Inc and will be identified using the same inclusion/exclusion criteria

4.1 Inclusion Criteria

1. Age ≥66
2. Member of Pro-Health Practice for ≥3 years
3. Determined to be an appropriate candidate as evidenced by ANY of the following:
    a. Multiple Chronic Conditions (presence of ≥3 active health problems)
    b. >10 medications
    c. ≥ 1 hospitalization over the past year
    d. ≥2 emergency department visits over the past year
    e. Seen by >2 specialists (excluding GYN and eye) over the past year

4.2 Exclusion Criteria

1. Unable to consent (e.g. dementia)
2. In hospice or meeting hospice criteria
3. End stage renal disease
4. Not English speaking
5. Nursing home resident

5 STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

The elicitation of goals will be embedded into clinical programs routinely offered to patients with MCC. Specially trained Goals Facilitators will be trained to elicit **S**pecific, **M**easurable, **A**ttainable, **R**ealistic, and **T**imely (SMART) goals from their patients. Primary Care Clinicians and participating cardiologists will work with Goal Facilitators to ensure the goals are communicated and care decisions are made based upon patients. SMART goals and care preferences and such decisions and rationales are documented in the EHR.

The core components of Priorities Care include:

1. Each patient's specific, measurable, actionable, and reliable health outcome priorities (the realistic health and life outcomes they want from their health care) & care preferences (what they are willing and able to do for their health and to achieve their outcome goals) are elicited by a trained member of the health care team (most likely an RN or APRN) & shared in an easily accessible location in the EHR (and transmitted to specialist using the same method as other related patient information is transmitted).
2. Primary and specialty (cardiologists to begin with) clinicians: a) agree on roles and responsibilities appropriate for each patient (compacts); b) Translate each patient's health outcome priorities and care preferences into care options; and c) chose diagnostic and therapeutic interventions with patients (and caregivers when appropriate) that are most consistent with each patient's health priorities and preferences within the context of their health conditions.
3. Primary and specialty clinicians align their care with each patient's outcome priorities & care preferences by moving to decision making that bridges disease-based evidence with goals & preferences within context of uncertainty, prognosis, competing conditions, treatment complexity, trade-offs (See ***Figures 2*** and ***3***)

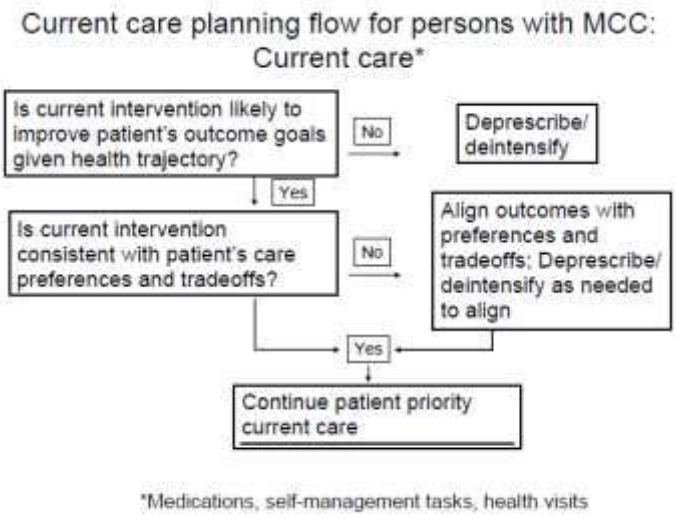


Figure 2

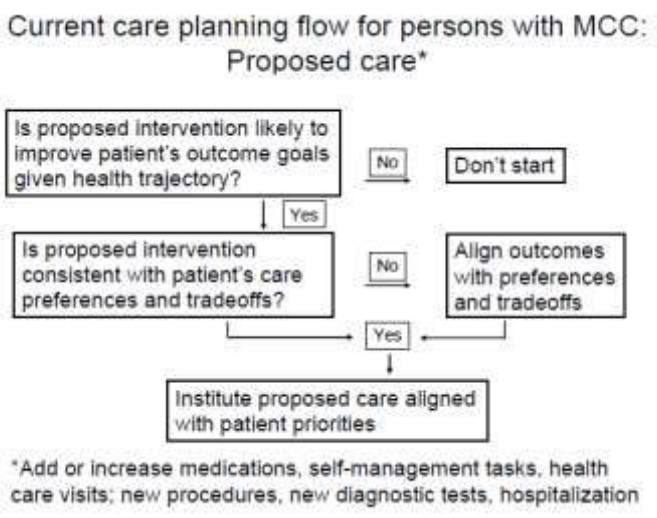


Figure 3

Modifications to Study Intervention

We will use the effectiveness-implementation hybrid design Type 1, which allows us to identify barriers and facilitators to real world implementation and modifications that should be made to maximize implementation while also assessing effectiveness. This design is appropriate because there is strong face validity for Patient Priorities Care, indirect evidence supporting it, and minimal risk.

This endeavor will be conducted in a series of steps using continuous quality improvement (CQI) to test the viability of implementing Patient Priorities Care into a "real-world" primary care practice. This will be done in a step-wise fashion; starting with one primary care provider and a small number of patients then broadening this to other providers within the same practice and eventually to a larger number of practices within the group. Participants who are enrolled during the initial study phase will be considered 'pre-pilot.'

5.2 Handling of Study Interventions

Goal Facilitators

The Goal Facilitators will be a trained health professional (e.g. nurse, social worker, case worker).

Responsibilities

1. Undergo training and preparation to elicit and document patients' health outcome goals and care preferences
2. Elicit goals using PPC point-of-care materials.
3. Communicate these goals back to the Primary Care Provider through verbal discussion and/or documentation into the patient's Electronic Health Record (EHR).
4. Enter the identified SMART Goals into Electronic Health Record (EHR) and provide to patients (as applicable).
5. Review health outcome goals and care preferences and update as needed

Clinicians

The clinician will be a licensed health care professional (MD, APRN, PA).

Responsibilities

1. Know or review patient's goals and care preferences template provided by the goal facilitators, align care decisions to each patient's specific goal, and respond to specific patient "asks"
2. Decision making moves
    a. From: *You need (fill in blank) for your (fill in blank).*
    b. To: *There are different things that we could do. But knowing your conditions, your overall health, and your health outcome goals and care preferences (what matters most to you), I suggest we try (fill in the blank).*
3. Participate in health priorities aligned care training followed by ongoing learning collaboratives Translate patient's health priorities into care options with guidance from point-of-care materials, decision algorithms, and clinician champion

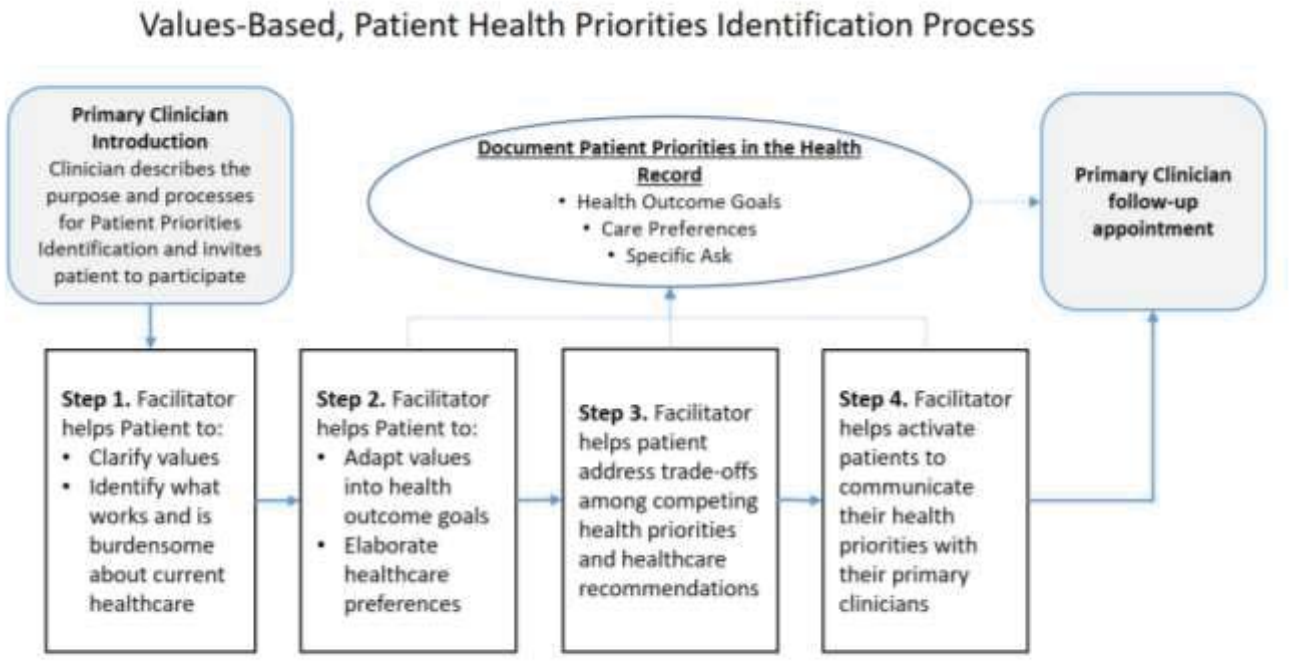
4. Participate with patients/caregivers in shared decision-making around outcome priorities and care preferences
5. Review, discuss, and update patient's health priorities or refer to facilitator for further discussion
6. Include patient health outcome priorities and care preferences in clinical communications such as referrals, consults, clinical notes, hospital admission and discharge notes.
7. Discuss with specialists (e.g. cardiologists) as needed to ensure care is aligned with patient's priorities
8. Document discussions and decisions in EHR (SMART phrases)

6 STUDY PROCEDURES

6.1 Schedule of Evaluation for Patient Population

Time Period	Screening	Informed Consent (Enrollment)	Goal Facilitation Visits*	PPC Clinician Visits*	Interviews (Patient Reported Outcomes)	Medical Records Collection
Enrollment (Day 1)	x	x			x	x
Study Duration			x	x		
Follow-up Evaluation (Year 1)					x	x

*Intervention Group Only



6.2 Description of Research Assessments and Evaluations

6.2.1 Screening Evaluation

Potentially eligible patients will first be identified by administrative data within the Electronic Health Record (EHR). In the intervention arm, the primary care clinician will review the list and refer patients to a Goal Facilitator at the practice who will be responsible for obtaining informed consent to participate in the PPC program. The control group will be identified through the same electronic health record search.

6.2.2 Consent and HIPAA Authorization

We will require a full waiver of consent and HIPAA authorization for the health care utilization that will be used as part of the screening process and evaluation of the patient population. We will also request a waiver of signed consent and HIPAA authorization for participation of clinicians and patients in the research evaluation. It would be impractical to gain signed consent for this information, specifically for this population and the research involves minimal risk.

Interviews will be conducted primarily over the phone by a trained project staff member from Yale. For patients enrolled through the primary clinic, ProHealth staff will identify the individuals who have consented, add their contact information into a secure electronic data collection system (REDCap) which project staff will use to contact the participants to administer the survey in a separate database. Contact information will be stored separately from interview and medical record data and destroyed once the surveys have been conducted and data collection and cleaning is complete.

Intervention Group

Once intervention participants have been identified and invited to participate in the PPC program by their PCP, the goal facilitators will obtain verbal consent and HIPAA authorization. In the case that a potential participant does not meet the criteria to provide informed consent, they will be excluded. Participants in the intervention group will not receive payment.

Control Group

The matched group controls will receive a recruitment letter from their clinician describing the research and interview. Patients will be able to opt-out if they do not wish to be contacted by returning a post card. For patients who do not opt-out, a centralized, trained research staff member will contact candidates by phone to confirm eligibility and to obtain verbal consent for enrollment in the control arm which involves standard clinical care, data collection through an interview, and a medical record review. Participants in the control group will receive $10 for each research interview for a total reimbursement of $20.

Both Groups

Although this study involves minimal risk, every effort will be made to ensure that all potential participants understand the details of the study, what will be asked of them as a participant, and the high statues of confidentiality that will be maintained. Additionally, it will be made clear that refusing to participate will not affect eligibility to receive services or benefits. Potential participants will be asked to demonstrate their understanding of what participation involves. If it is unclear that participants demonstrate full understanding of what is being asked of them, staff will continue the discussion until consent has been fully clarified.

6.2.3 Assessments and Data Collection

Quantitative Data

See Appendix B for the data collection plan for the quantitative evaluation of the PPC pilot program.

Qualitative Data

For qualitative interviews, the audio-recordings will be transcribed and transcripts will be coded by 2-3 trained members of the research study. Qualitative interviews are analyzed using the constant comparative methodology. All coded material will be de-identified and aggregated for data analysis.

7 SAFETY ASSESSMENTS

It is the responsibility of the PI to oversee the safety of the study. Research data will be reviewed in a timely manner; communication with the IRB will be documented in an open and timely manner in accordance with existing policies; source documentation will exist for all data fields/questions; explanations for deviations from the study protocol will be recorded; and all study files and documents will be maintained in organized files. Medical monitoring will include a regular assessment of the number and type of unanticipated problems.

The IRB will also determine whether currently or previously enrolled participants should receive notice of the unanticipated problem (and the potential for possible risk).

7.1 Data Safety Monitoring Plan

This protocol presents minimal risks to the subjects and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), including adverse events, are not anticipated. In the unlikely event that such events occur, Reportable Events [which are events that are serious or life-threatening and unanticipated (or anticipated but occurring with a greater frequency than expected) and possibly, probably, or definitely related] or Unanticipated Problems Involving Risks to Subjects or Others that may require a temporary or permanent interruption of study activities will be reported immediately (if possible), followed by a written report within 5

calendar days of the Principal Investigator becoming aware of the event to the IRB (using the appropriate forms from the website). The investigator will apprise fellow investigators and study personnel of all UPIRSOs and adverse events that occur during the conduct of this research project via email as they are reviewed by the principal investigator and later during an in-person meeting with the team**.**

8 RISKS AND BENEFITS

8.1 Risks

Patient Priorities Care conversations will be integrated as part of clinic standard of care (as part of goals of care conversations). Potential risks are limited to breach of confidentiality and any discomfort that might arise while discussing a patient's values/preferences/goals. Potential risks are minimal, no more than encountered in everyday life, with the potential benefits far outweighing the risks.

8.2 Benefits

The potential benefit of the evaluation of this new clinical approach will be to disseminate Patient Priorities Care. We expect that this approach will create an enhanced dialogue between patients and their clinicians and will result in better care for the individual.

9 STATISTICAL CONSIDERATIONS

9.1 General Design Issues

This is a pilot study. We will work with the experienced Yale Program on Aging evaluation team within the Operations and Biostatistical Cores to develop the sampling and statistical methodologies needed for process and outcomes comparison. For example, to evaluate patient and caregiver reported outcomes, we will need to match patients from non-intervention practices in ProHealth who are similar to patients participating in patient-priorities care. We will follow standard methodologies developed by our experts.

9.2 Sample Size and Randomization

As this is a pilot study, we did not complete a formal sample size calculation. The chosen sample size is based upon the estimated number of patients seen in the practice over the course of the year.

9.3 Outcomes

9.4.1 Primary outcomes

The primary outcome measures will be (1) the total score for the Treatment Burden Questionnaire (TBQ)[16], a 15-item measure to assess treatment burden among patients

with one or more chronic conditions, (2) the total score for the Older Patient Assessment of Chronic Illness Care (O-PACIC),[17] a 10-item measure to assess chronically-ill patients' perceptions of the degree to which health care delivery is integrated and coordinated, (3) CollaboRATE,[18] a 3-item patient-reported measure, of shared decision making in clinical encounters, and (4) measures of changes in health care utilization drawn from review of patient medical records. The primary outcome measures will be collected during the baseline and follow-up (6-12 months) telephone interviews.

9.4.2 Secondary outcomes

Secondary outcome measures will be (1) subscales of the O-PACIC (i.e., patient activation, delivery system design/support, goal setting, problem-solving/contextual counseling, and follow-up/coordination) and (2) items from the TBQ that assess self-management tasks, medical visits, laboratory tests and other examinations, relationships with providers, medications.

9.4 Data Analyses

We will calculate descriptive statistics for the intervention and control participants' baseline characteristics and primary and secondary outcomes. Mean differences between the two groups' post-test primary and secondary outcome scores will be examined using multivariable linear regression analysis (adjusting for baseline demographic and clinical characteristics). Linearity assumptions will be checked graphically and deviations from model additivity will be addressed by testing clinically indicated two-way interactions. Models will be evaluated by inspecting residual plots and goodness-of-fit statistics. To account for clustering of patients within medical practices, we will estimate models with robust standard errors. To minimize the loss of observations used in the analyses, we will use fully-conditional multiple imputation to address missing data. Comparability of participants in the two arms will be assessed by comparing the distribution of baseline characteristics in the two groups using appropriate graphical procedures, summary statistics and multivariable methods. If participants' baseline characteristics appear to be unbalanced between arms, we will use inverse propensity score weighting to achieve covariate balance between the two groups.

10 DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

A trained research staff at ProHealth will be responsible for entry of screening, enrollment, and medical records into REDCap. Data inconsistencies and data abstraction errors will be dealt with

initially by telephone or email with the research staff, possibly augmented by webinar-based training, and troubleshooting sessions.

10.2 Data Management

Data coordination and management will occur within the Yale School of Medicine's Program on Aging (POA). Data management procedures will ensure accurate and efficient data collection and analysis; confidentiality and real-time, on-demand study monitoring reports.

All data will be maintained in accordance with HIPAA guidelines for participant confidentiality and privacy. All data will reside on secure, HIPAA-compliant database and file-sharing resources managed by Yale Information Technology Services (ITS). Access to data resources will be strictly limited to research staff and investigators, and all such resources will reside on a local network not accessible outside the secure Yale environment. Direct identifiers used to facilitate follow-up interviews and outcomes evaluation will be stored in a separate database to which access will be further restricted on a need-to-know basis.

Full backups of application software and study data are performed by Yale ITS daily. In addition, Program on Aging/Data Management Informatics Center (POA/DMIC) maintains a separate backup schedule of the REDCap database, to facilitate rapid recovery of individual records should that ever be necessary. All electronic quantitative data will be stored in REDCap and on a secure server. For the qualitative interviews, the names and phone numbers used to contact the participants will not be linked, will be kept separate from any other data, and will be destroyed as soon as the survey is administered. Coding of de-identified transcriptions will be performed by researchers at Yale University and NYU.

10.3 Quality Assurance

10.3.1 Training

Training for Patient Priorities Care facilitators and clinicians will follow an ongoing collaborative learning process. This includes the following feedback and decisional guidance mechanisms for the clinicians:

- Training processes and point-of-care materials for facilitators, patients and clinicians developed, implemented, and modified with input from national experts.
- Initial, face-to-face training sessions with facilitators and clinicians. These trainings will be based on clinical scenarios and communication scripts.
- In the early stages, national experts will participate in telephonic training with clinicians and facilitators. Clinicians will discuss their PPC patients and clinicians' will share their experiences with clinical decision-making aligned with patient priorities.

- Throughout the project, there will be monthly in-person meetings with PPC investigators and Primary Care Providers (PCPs). In addition, there will be bi-monthly in-person PPC team meetings with cardiologists.
- In the later stages of the project, PCPs will conduct weekly meetings led by a local clinical champion. Clinicians will discuss a PPC patient and clinicians' will share their experiences with clinical decision-making aligned with patient priorities.

Point-of-care material and tips and scripts for facilitating patient priorities identification and for participating in patient priorities decision-making and care developed and modified based on feedback and ongoing experiences

11 PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

This protocol and the informed consent script and any subsequent modifications will be reviewed and approved by the IRB or ethics committee responsible for oversight of the study.

11.2 Participant Confidentiality and Security

Information about study participants will be kept confidential and managed according to the requirements of HIPAA. In the event that a participant revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of participant authorization. For participants that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the participant is alive) at the end of the follow-up period.

Any data, forms, reports, video recordings, and other records that leave the research sites will be identified only by a participant identification number (Participant ID, PID) to maintain confidentiality unless permission is granted by the participant for non-research purposes such as press releases or dissemination. All paper records will be kept in a locked file cabinet. Researchers at external institutions will not have access to identifying information. For the qualitative interviews, at the completion of the coding and analysis the recordings and the link between study ID and identifying information will be destroyed, thus rendering the data anonymous.

All study data collection forms and follow-up schedules will be managed using REDCap, a secure, web-based data collection and workflow management system developed at Vanderbilt and supported by the national CTSA program. REDCap has been certified by Yale's Information Compliance Office as meeting HIPAA privacy and security guidelines. Identifying information will not be released without written permission of the participant, except as necessary for

monitoring by IRB, the study sponsors, and the OHRP.

11.3 Study Discontinuation

The study may be discontinued at any time by the IRB, the funding agencies, the Office of Human Research Protections (OHRP), or other government agencies as part of their duties to ensure that research participants are protected.

12 REFERENCES

1. Bayliss EA, Bonds DE, Boyd CM, et al. Understanding the context of health for persons with multiple chronic conditions: moving from what is the matter to what matters. The Annals of Family Medicine. 2014;12(3):260-269.
2. American Geriatrics Society. Guiding principles for the care of older adults with multimorbidity: an approach for clinicians: American Geriatrics Society Expert Panel on the care of older adults with multimorbidity. J Am Geriatr Soc 2012; 60: e1–25.
3. Uhlig K, Leff B, Kent D, Dy S, et al. A framework for crafting clinical practice guidelines that are relevant to the care and management of people with multimorbidity. J Gen Intern Med. 2014;29(4):670-9.
4. Tinetti ME, Naik AD, Dodson JA. Moving from disease-centered to patient goals–directed care for patients with multiple chronic conditions. JAMA Cardiol 2016: 1(1):9-10.
5. Tinetti ME, Fried TR, Boyd CM. Designing health care for the most common chronic condition: Multi-morbidity. 2012. JAMA 307(23):2493-4.
6. Lorgunpai SJ, Grammas M, Lee DSH, McAvay G, Charpentier P, Tinetti ME. Potential therapeutic competition in community-living older adults in the U.S.: Use of medications that may adversely affect a coexisting condition. PLoS ONE 9(2): e89447.
7. Zulman DM, Sussman JB, Chen X, Cigolle CT, Blaum CS, Hayward RA. Examining the evidence: a systematic review of the inclusion and analysis of older adults in randomized controlled trials. J Gen Intern Med. 2011;26(7):783-90.
8. O'Hare AM, Hotchkiss JR, Kurella et al. Interpreting treatment effects from clinical trials in the context of real-world risk information: end-stage renal disease prevention in older adults. JAMA Intern Med. 2014;174(3):391-7.
9. Fried TR, Tinetti ME, Iannone L, O'Leary JR, Towle V, Van Ness PH. Health Outcome Prioritization as a Tool for Decision Making among Older Persons with Multiple Chronic Conditions. Arch Intern Med, 2011; 171: 1854 – 1856.
10. Montori VM, Brito JP, Murad MH. The optimal practice of evidence-based medicine: incorporating patient preferences in practice guidelines. JAMA. 2013;310(23):2503-4.
11. Institute of Medicine (IOM). Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, D.C: National Academy Press; 2001.
12. Childers JW, Back AL, Tulsky JA, Arnold RM. REMAP: A Framework for Goals of Care Conversations DOI: 10.1200/JOP.2016.018796 Journal of Oncology Practice 13, no. 10 (October 2017) e844-e850.
13. Austin CA, Mohottige D, Sudore RL, Smith AK, Hanson LC. Tools to promote shared decision making in serious Illness: A systematic review. JAMA Intern Med. 2015;175(7):1213-22.
14. Sudore RL, Knight SJ, McMahan RD, et al. A novel website to prepare diverse older adults for decision making and advance care planning: a pilot study. J Pain Symptom Manage. 2014;47(4):674-86.
15. Bernacki RE, Block SD; American College of Physicians High Value Care Task Force. Communication about serious illness care goals: a review and synthesis of best practices. JAMA Intern Med. 2014 Dec;174(12):1994-2003.
16. Tran, V., Harrington, M., Montori, V., Barnes, C., Wicks, P., Ravaud, P. (2014). Adaptation and validation of the Treatment Burden Questionnaire (TBQ) in English using an internet platform. BMC Medicine, 12, 109-117.
17. Cramm, J. & Nieboer, A. (2013). Development and validation of the Older Patient Assessment of Chronic Illness Care (O-PACIC) Scale after hospitalization. Social Indicators Research, 116(3), 959-969.
18. Elwyn, G., Barr, P., Grande, S., Thompson, R., Walsh, T., Ozanne, E. (2013). Developing CollaboRATE: A fast and frugal patient-reported measure of shared decision making in clinical encounters.

APPENDIX A: GOALS AND PREFERENCES TEMPLATE

Patient Priorities Care: Health Priorities Template

Current Function and Support:

Health trajectory (Current understanding of how health will likely change over the next few years):

Matters most (Values):

SMART Health Outcome Goals

1.

2.

3.

Helpful care: The medications, self-management tasks, clinical visits, tests, or procedures, that I think are helping me most with my health goals and I can do them without too much difficulty

1.

2.

3.

Difficult or bothersome care: The medications, self-management tasks, clinical visits, tests, or procedures that don't think are helping my goals and are bothersome or too difficult for me. I would like to talk with my doctor about whether these are helping my goals. If not, can I stop them or cut back? If they are helping, is there a way to make them less bothersome or less difficult?

1.

2.

3.

Specific ask (One Thing): The one thing I most want to work on is (*fill in a health problem that you think is keeping you from achieving your health outcome goal OR the healthcare task that is most bothersome or difficult*) so that I can do more of (fill in health outcome goal).

Priorities Facilitator:		**Phone/Email:**	

APPENDIX B: DATA COLLECTION ELEMENTS

General Characteristics of Practice, Intervention, and Participants

	Domain	Time Period
1	Practice Characteristics	Study Initiation
2	Patient Demographics Control vs. Intervention	Screening
3	Recruitment- referral by PCP	Screening
4	Payer Source	Enrollment
5	Clinician (PCP & Cardiology) PPC Documentation in patient records	Enrollment through1 year
6	Facilitator Visits	Enrollment through 1 year
7	Comorbidities	1 year prior to enrollment

Utilization Outcomes

	Domain	Time Period
8	Medication (Secondary Outcome)	Enrollment through1 year
9	Referral/Consult (Secondary Outcome)	Enrollment through 1 year
10	Testing (Secondary Outcome)	Enrollment through 1 year
11	Self-Management (Secondary Outcome)	Enrollment through 1 year
12	Procedures (Secondary Outcome)	Enrollment through1 year
13	Social Changes (Secondary Outcome)	Enrollment through 1 year

Patient Reported Outcomes

	Domain	Time Period
14	Global Physical and Mental Health Instrument: Promis v1.2	Enrollment and Follow-up (6-12 months)
15	Integrated care Instrument: O-PACIC (Primary Outcome)	Enrollment and Follow-up (6-12 months)
16	Shared decision-making Instrument: collaboRATE	Enrollment and Follow-up (6-12 months)
17	Cognition Instrument: MOCA (recall item)	Enrollment and Follow-up (6-12 months)
18	Treatment burden Instrument: TBQ (Primary Outcome)	Enrollment and Follow-up (6-12 months)